Docket No.: 21059/0206916-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Bakulesh Khamar et al.

Application No.: 10/565,211 | Confirmation No.: 9175

Filed: October 30, 2006 | Art Unit: 1645

For: PROCESS FOR MANUFACTURING PHARMACEUTICAL COMPOSITION COMPRISES OF MYCOBACTERIUM W IN THE TREATMENT OF ASTHMA (OBSTRUCTIVE LUNG DISEASE) | Examiner: R. P. Swartz

DECLARATION OF DR. MICHAEL ROSS UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Dear Sir:

Dr. Michael A Ross, declares under penalty of perjury under the laws of the United States of America as follows:

(1) I have received a M.D.in 1975 from the George Washington University School of Medicine. I am currently the President at CPL, Inc., division of Cadila Pharmaceuticals Ltd., where I entered employment in 2007. The assignee of the present application is Rajiv Indravadan Modi, who is the Managing Director of Cadila Pharmaceuticals Ltd. I currently hold three University appointments in two different specialties at three universities. I have taught medicine at these institutions for 28 years as well as seen patients. My field of research has been focused on breast and cervical cancer as well as antibiotic use in Obstetrics and Gynecology. I currently sit on

the Center For Disease Control Panel on Prevention of Cervical and Breast Cancer. I have 2 peer-reviewed publications in academic journals.

(2) While I am not an inventor on the present application, I am familiar with the subject matter and claims of the present application.

(3) I reviewed the Examiner's rejections in the Actions of October 16, 2007 and June 9, 2007. The Examiner rejected Claims 22-48 because the Examiner concluded that "the claimed subject matter was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is most nearly connected, to make and/or use the invention." Specifically, the Examiner required information such as "the actual composition administered to the patients (whole cells, disrupted cells, cell fractions, etc.), the dosage administered, the route of administration, and the frequency of administration."

(4) I reviewed the '211 application in its entirety including the written description and the claims. I conclude that one of ordinary skill in the art at the time of the filing of the '211 application would have been able to practice the claimed invention after having read the application. Specifically, regarding composition, I note that Example 1 teaches a therapeutic compositions in which a dosage includes 0.1 ml of therapeutic agent. Example 1 further teaches that compositions A, B, C and J contain heat killed whole cell Mycobacterium w, composition D contains extract of Mycobacterium w after sonication (i.e., after cell disruption), and compositions E to I contain cell fraction extracted Mycobacterium w.

(5) Regarding dosage, Example 6 teaches giving patients 0.1 ml doses at a rate of 1 per week. Example 4 teaches treating the patient once a week for four weeks while example 7 teaches treating patients according to a conventional therapy for three months followed by a conventional therapy with Mycobacterium w for an additional three months.

(6) Regarding the route of administration, Example 4 states that the patient "was given Mycobacterium w intradermally at the interval of one week." Further pages 2-3 of the specification

teach that asthma medications may be inhaled or taken orally with the preferred method being inhalation.

(7) Regarding frequency, both Examples 4 and 6 state that pharmaceutical compositions containing Mycobacterium w was administered "at the interview of one week."

(8) Based on the cited specific compositions, dosages, routes of administration, and frequencies of administration in the '211 application, I conclude that one of ordinary skill in the art at the time of the filing of the '211 application having read the application would have been able to practice the claimed invention without undue experimentation. One of ordinary skill would understand (1) that the appropriate therapeutic dosage is approximately 0.1 ml of Mycobacterium w, (2) the dosage may include whole cells, sonicated cells, or extracted cell fractions, (3) the composition should be administered approximately once per week, and (4) treatment should be continued from four weeks to three months.

(9) I have also reviewed the accompanying Rule 132 declaration of Dr. Khamar. In this declaration, he provides further clarifications as to how the examples were reduced to practice by the inventors. The additional data in the Rule 132 declaration of Dr. Khamar are nothing more than minor details that someone practicing medicine or doing medical research would find routine and well-known in the field of medicine. The additional data in the Rule 132 declaration of Dr. Khamar supplements the specification, which clearly provides enough details as explained above to a person practicing medicine or doing medical research to practice the invention of Dr. Khamar and his co-inventors.

(10) I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed at Gaithersburg, Maryland, United States of America, on this 11 day of December 2007.

Michael Ross, M.D.